

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re Selenious Acid Litigation

No. 2:24-cv-07791-BRM-CLW (Consolidated)

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**[PROPOSED] ORDER GRANTING
PRELIMINARY INJUNCTION**

Plaintiff American Regent, Inc. (“ARI”) has moved for a Preliminary Injunction Order pursuant to Federal Rule of Civil Procedure 65(a) and Local Civil Rule 65.1(a). In consideration of the entire record, ARI has demonstrated that it is likely to succeed on the merits of its patent infringement allegations against Defendants.¹ Defendants have not presented a substantial question on the validity of the asserted patent claims. In addition, ARI has demonstrated that it is likely to suffer irreparable harm from Defendants’ infringement and that the balance of equities

¹ ARI originally sued fourteen Defendants. *See American Regent, Inc. v. Accord Healthcare, Inc.*, C.A. No. 2:24-cv-07791-BRM-CLW; *American Regent, Inc. v. Aspiro Pharma Ltd.*, C.A. No. 24-cv-07794-BRM-CLW; *American Regent, Inc. v. Cipla USA, Inc. et al.*, C.A. No. 2:24-cv-07796-BRM-CLW; *American Regent, Inc. v. Dr. Reddy’s Laboratories, Ltd et al.*, C.A. No. 2:24-cv-07799-BRM-CLW; *American Regent, Inc. v. Eugia Pharma Specialities Ltd. et al.*, C.A. No. 2:24-cv-08956-BRM-CLW; *American Regent, Inc. v. Fresenius Kabi USA, LLC*, C.A. No. 2:24-cv-07801-BRM-CLW; *American Regent, Inc. v. Gland Pharma Limited*, C.A. No. 2:24-cv-07802-BRM-CLW; *American Regent, Inc. v. Hikma Pharmaceuticals USA, Inc.*, C.A. No. 2:24-cv-07803-BRM-CLW; *American Regent, Inc. v. Long Grove Pharmaceuticals, LLC*, C.A. No. 2:24-cv-07804-BRM-CLW; *American Regent, Inc. v. RK Pharma, Inc.*, C.A. No. 2:24-cv-07805-BRM-CLW; *American Regent, Inc. v. Somerset Therapeutics, LLC et al.*, C.A. No. 2:24-cv-07807-BRM-CLW; *American Regent, Inc. v. Sun Pharmaceutical Industries Limited et al.*, C.A. No. 2:24-cv-07810-BRM-CLW; *American Regent, Inc. v. Xiromed, LLC et al.*, C.A. No. 2:24-cv-07811-BRM-CLW; *American Regent, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, C.A. No. 2:24-cv-07812-BRM-CLW. Four defendants entered into a consent judgment or dismissal—Long Grove, Sterisience, Fresenius, and Eugia—leaving Aspiro, Gland, Somerset, Accord, Zydus, Xiromed, DRL, Cipla, Hikma, Sun Pharma, and RK Pharma as the remaining consolidated Defendants.

and the public interest favor protecting ARI and granting a preliminary injunction. ARI's Motion for a Preliminary Injunction is therefore GRANTED.

Accordingly, IT IS HEREBY ORDERED that:

1. Defendants, their affiliates, subsidiaries, officers, agents, servants, attorneys, representatives and employees, and any and all persons or entities acting by, through, under, or in active concert with any or all of them are hereby enjoined and restrained until further order from this Court from manufacturing, using, offering to sell, selling, promoting, advertising, marketing, servicing, distributing, supplying, or otherwise introducing into the stream of commerce within the United States, or importing into the United States any generic selenious acid injection product that is, or would be, the subject of the Abbreviated New Drug Application ("ANDA") Nos. 218655, 219633, 218661, 218639, 219629, 217680, 218536, 218780, 219547, 219476, or 219322 ("Defendants' ANDAs"), including any generic selenious acid injection product in unit forms (1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and/or (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL).

2. Within five (5) business days of this Order, Defendants shall provide Plaintiffs and the Court with the specific quantity, location, and price of any generic selenious acid injection product that Defendants, their affiliates, subsidiaries, officers, agents, servants, attorneys, representatives, employees, and customers, and any and all persons or entities acting by, through, under, or in active concert with any or all of them, have manufactured, acquired, provided, distributed, purchased, supplied, or stored within the United States, or imported into the United States, for the purpose of selling, offering to sell, or otherwise introducing into the stream of commerce within the United States.

3. Within five (5) business days of this Order, Defendants shall provide notice of this Order to any affiliates, subsidiaries, officers, agents, servants, attorneys, representatives, employees, and customers, and any and all persons or entities acting by, through, under, or in active concert with any or all of them that are involved in any effort to manufacture, use, offer to sell, sell, purchase, promote, advertise, market, service, distribute, supply, or otherwise introduce into the stream of commerce within the United States, or import into the United States, any generic selenious acid injection product, or any product that is the subject of Defendants' ANDAs, such that the above persons and entities are duly noticed and bound by this Order under Federal Rule of Civil Procedure 65(d)(2). Defendants shall further provide proof of each such notice to this Court by filing it within ten (10) business days of this Order.

4. IT IS FURTHER ORDERED that this Preliminary Injunction shall remain in full force and effect until further order of the Court.

The Honorable Brian R. Martinotti
United States District Judge